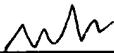




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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,238	08/01/2003	Tilak M. Shah	4179-126	2458
23448	7590	06/02/2005	EXAMINER	
INTELLECTUAL PROPERTY / TECHNOLOGY LAW			FIDEI, DAVID	
PO BOX 14329			ART UNIT	PAPER NUMBER
RESEARCH TRIANGLE PARK, NC 27709			3728	
DATE MAILED: 06/02/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,238	SHAH, TILAK M.	
	Examiner	Art Unit	
	David T. Fidei	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 01 August 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 9/2/03.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

Election/Restrictions

1. Claims 18-20 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 16, 2005.

2. Applicant's election with traverse of the invention of Group I in the reply filed on May 16, 2005 is acknowledged. The traversal is on the ground(s) that the inventions are not independent. This is not found persuasive because this is only one consideration in determining the properness of a restriction requirement. As stated in M.P.E.P. 821.01 a large number of subjects can be restricted even though they are "dependent".

The term "independent" as already pointed out, means not dependent. A large number of subjects between which, prior to the 1952 Act, division had been proper, are dependent subjects, such as, for example, combination and a subcombination thereof; as process and apparatus used in the practice of the process; as composition and the process in which the composition is used; as process and the product made by such process, etc. If section 121 of the 1952 Act were intended to direct the Commissioner never to approve division between dependent inventions, the word "independent" would clearly have been used alone. If the Commissioner has authority or discretion to restrict independent inventions only, then restriction would be improper as between dependent inventions, e.g., the examples used for purpose of illustration above. Such was clearly not the intent of Congress. Nothing in the language of the statute and nothing in the hearings of the committees indicate any intent to change the substantive law on this subject. On the contrary, joinder of the term "distinct" with the term "independent", indicates lack of such intent. The law has long been established that dependent inventions (frequently termed related inventions) such as used for illustration above may be properly divided if they are, in fact, "distinct" inventions, even though dependent.

Hence the combination and subcombination, process and product made by the process, meet the criteria listed above. As to the consideration of the additional claims not presenting a burden.

"For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant.", see MPEP § 803.

Applicant has not provided any showings but merely alleges there is no serious burden. Insofar as the criteria for restriction practice establishes, there is a *prima facie* showing provided by the initial holding.

The requirement is still deemed proper and is therefore made FINAL.

Claim Construction

3. Applicant's In analyzing applicant's invention as set out in the pending claims, the examiner sets forth the following to aid in understanding the application of the prior art herein. Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim are not read into the claim. *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily). *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)), § MPEP 2106 (II)(c).

If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction, see

M.P.E.P. § 2111.02 "PREAMBLE STATEMENTS RECITING PUR-POSE OR INTENDED USE". A centrifugal tube is recited in the claims where this term is not seen as imparting any significance to the claim or tube per se.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-7, 10-13 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Tobler (Patent no. 5,255,808). A tubular member 2 is disclosed in figure 2 having a closed distal end at 3 and an open proximal end at 5, with integral hinge elements 6 at opposing sides thereof for facilitating flattening of the tube, see figure 7.

As to claim 2 the tube has a conical distal portion at 17, note figure 2.

As to claims 3, 4, the open proximal end of the tube comprises coupling structure, threads, for mateable engagement with a cap, see col. 3, lines 35-37.

As to claim 5, the integral hinge elements are diametrically opposite one another.

As claim 6, figure 10 discloses a tube comprising concave depressions on an exterior surface of the tube, oppositely facing one another, between the respective integral hinge elements 106.

As to claim 7, process by with the tube is formed, i.e., by a molding technique selected from the group consisting of extrusion blow molding and rotational molding, is not seen as imparting a distinguishing characteristics over the prior.

A "product by process" claim is directed to the product per se, no matter how actually made, *In re Hirao*, 190 USPQ 15 at 17 (footnote 3). See also *In re Brown*, 173 USPQ 685; *In re Luck*, 177 USPQ 523; *In re Fessmann*, 180 USPQ 324; *In re Avery*, 186 USPQ 161; *In re*

Wertheim, 191 USPQ 90; and In re Marosi et al, 218 USPQ 289, all of which make it clear that it is the patentability of the final product per se which must be determined in a "product by process" claim, and the an old or obvious product produced by a new method is not patentable as a product, whether claimed in "product by process" claims or not. During examination, the patentability of a product-by-process claim is determined by the novelty and non-obviousness of the claimed product itself without consideration of the process for making it which is recited in the claim. In re Thorpe, 227 USPQ 964 (Fed. Cir. 1985), M.P.E.P. § 2113.

As to claim 10, the tube of claim 1, wherein each of the integral hinge elements 6 that extends along substantially the full length of the tube between its proximal and distal ends.

As to claim 11, the integral hinge elements 6 extends along only part of the length of the tube between its proximal and distal ends.

As to claims 12, wherein each of the integral hinge elements comprises a ridged structure, note figure 3 where the integral hinge element 6 is ridged outward.

As to claim 13, each of the elements 6 are constructed similar to element 13, see col. 3 line 66 to col. 4 line 2 and comprises a corrugated protrusion structure, note figure 5.

As to claims 15 and 16, polypropylene is disclosed in col. 6, line 16.

As to claim 17 the tube has a closed distal end 3 and an open proximal end 5, with an elongate main body portion 2 of generally cylindrical form, with integral hinge elements 6 at opposing sides of the main body portion, extending longitudinally along at least a portion of the length thereof, whereby manual compressive pressure exerted on respective exterior surfaces of the main body portion between the integral hinge elements will effect flattening of the tube at a region of compression of the main body portion, see figure 7.

6. Claims 1-5, 7, 10-14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kasboske (Patent no. 6,170,712). A tubular member 14 is disclosed in figures 1-20 having a closed distal end at 3 and an open proximal end at 20, with integral hinge elements 30, 82, 100, 126 and 176 at opposing sides thereof for facilitating flattening of the tube, see col. 5, lines 55-65 where the volume of the structure is reduced.

As to claim 2, the tube has a conical distal portion in figures 4, 6 and 7.

As to claims 3, 4, the open proximal end of the tube comprises coupling structure, threads, for mateable engagement with a cap, see col. 5, lines 14-18.

As to claim 5, the integral hinge elements are diametrically opposite one another.

As to claim 7, process by with the tube is formed, i.e., by a molding technique selected from the group consisting of extrusion blow molding and rotational molding, is not seen as imparting a distinguishing characteristics over the prior.

A "product by process" claim is directed to the product per se, no matter how actually made, *In re Hirao*, 190 USPQ 15 at 17 (footnote 3). See also *In re Brown*, 173 USPQ 685; *In re Luck*, 177 USPQ 523; *In re Fessmann*, 180 USPQ 324; *In re Avery*, 186 USPQ 161; *In re Wertheim*, 191 USPQ 90; and *In re Marosi et al.*, 218 USPQ 289, all of which make it clear that it is the patentability of the final product per se which must be determined in a "product by process" claim, and the an old or obvious product produced by a new method is not patentable as a product, whether claimed in "product by process" claims or not. During examination, the patentability of a product-by-process claim is determined by the novelty and non-obviousness of the claimed product itself without consideration of the process for making it which is recited in the claim. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985), M.P.E.P. § 2113.

As to claim 10, the tube of claim 1, each of the integral hinge elements extend along substantially the full length of the tube between its proximal and distal ends.

As to claim 11, the integral hinge elements extends along only part of the length of the tube between its proximal and distal ends in that the hinge elements do not extend to the opening 20.

As to claims 12, wherein each of the integral hinge elements comprises a ridged structure, note figures 3, 5, 8, 11, 14 and 18 where the integral hinge element is ridged outward.

As to claim 13, each of the elements can also be viewed as comprising a corrugated protrusion structure, note figures 3, 5, 8, 11, 14 and 18.

As to claim 14, each of the integral hinge elements in figures 3, 5, 8, 11, 14 and 18 comprises a protrusion of generally triangular cross-section.

As to claim 17 the tube has a closed distal end 3 and an open proximal end 5, with an elongate main body portion 14, 80, 98, 124, 160, 210 of generally cylindrical form, with integral hinge elements 30, 82, 100, 126 and 176 at opposing sides of the main body portion, extending longitudinally along at least a portion of the length thereof, whereby manual compressive pressure exerted on respective exterior surfaces of the main body portion between the integral hinge elements will effect flattening of the tube at a region of compression of the main body portion, see col. 5, lines 55-65 where the volume of the structure is reduced.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasboske (Patent no. 6,170,712). The difference between the claimed subject matter and Kasboske resides in the device having an inner diameter on the order of 1 inch and a length of from about 3 to about 8 inches. Nothing is mentioned in Kasboske regarding the dimension of the container, but col. 5, lines 8-13 contemplates some uses for the container.

However, a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955). Also, it has been held that where the only difference between the prior art device and the claimed device was a recitation of relative dimensions, the claimed device was not patentably distinct from the prior art device, *Gardner v. TED Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. Denied, 469 U.S. 830, 2325 USPQ 232 (1984), see M.P.E.P. 2144.04 (IV). It would have been an obvious matter of design choice to construct the container having an inner diameter on the order of 1 inch and a length of from about 3 to about 8 inches, since such a modification would have involved a mere change in the size of a component dependent upon how big or small one desires to package the contents of col. 5, lines 8-13.

10. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tobler (Patent no. 5,255,808). The difference between the claimed subject matter and Tobler resides in the device having an inner diameter on the order of 1 inch and a length of from about 3 to about 8 inches. Nothing is mentioned in Tobler regarding the dimension of the container. However, a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955). Also, it has been held that where the only difference between the prior art device and the claimed device was a recitation of relative dimensions, the claimed device was not patentably distinct from the prior art device, *Gardner v. TED Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. Denied, 469 U.S. 830, 2325 USPQ 232 (1984), see M.P.E.P. 2144.04 (IV).

It would have been an obvious matter of design choice to construct the container having an inner diameter on the order of 1 inch and a length of from about 3 to about 8 inches, since such a modification would have involved a mere change in the size of a component dependent upon how big or small one desires to package the contents of the bottle.

REPLY BY APPLICANT OR PATENT OWNER TO THIS OFFICE ACTION

11. “In order to be entitled to reconsideration or further examination, the applicant or patent owner must reply to every ground of objection and rejection in this Office action. The reply must present arguments pointing out the specific distinctions believed to render the claims, including any newly presented claims, patentable over any applied references. The applicant ’s or patent owner ’s reply must appear throughout to be a bona fide attempt to advance the application or the reexamination proceeding to final action. A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references does not comply with the requirements of this section. The reply must be reduced to writing (emphasis added)”, see 37 CFR 1.111 (b) & (c), M.P.E.P. 714.02.

Pointing out specific distinctions means clearly indicating in the written response what features/elements or distinctions have been added to the claim/claims, where support is found in the specification for such recitations and how these features are not shown, taught, obvious or inherent in the prior art.

If no amendments are made to claims as applicant or patent owner believes the claims are patentable without further modification, the reply must distinctly and specifically point out the supposed errors in the examiner ’s action and must respond to every ground of objection and rejection in the prior Office Action in the same vain as given above, 37 CFR 1.111 (b) & (c), M.P.E.P. 714.02.

The examiner also points out, due to the change in practice as affecting final rejections, older decisions on questions of prematurity of final rejection or admission of subsequent amendments do not necessarily reflect present practice. “Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant’s amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c)” (emphasis mine), see MPEP 706.07(a).

Drawings

12. The photographs are objected to under 37 CFR 1.83(a) because they fail to show the subject matter as described in the specification in a clear manner. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fidei whose telephone number is (571) 272-4553. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David T. Fidei
Primary Examiner
Art Unit 3728

dtf
May 25, 2005